Jim Doyle
Governor

Karen E. Timberlake
Secretary

State of Wisconsin

Department of Health and Family Services

DIVISION OF PUBLIC HEALTH

1 WEST WILSON STREET
P O BOX 2659
MADISON WI 53701-2659

608-266-1568
FAX: 608-261-6392
dhfs.wisconsin.gov

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To: First Responder and Ambulance Service Providers
Service Medical Directors
EMS Training Centers
Hospitals

From: Brian Litza, Chief
Wisconsin Emergency Medical Services Section

Re: Welch Allyn AED 10 Recall

The state EMS office has received the following notifications regarding Welch Allyn AED's. If you have or know of people that have these devices please pass on this information.

Important Notice for All Welch Allyn AED 10 Customers

If you purchased a Welch Allyn AED10 or MRL JumpStart defibrillator your product may be subject to the voluntary recall we initiated on February 25, 2009. Depending upon the date of manufacture, your unit may have a remote chance of having one or more of the following problems:

- **Low Energy Shock**
- **Electromagnetic Noise Interference**
- **Unexpected Shutdown During Use**
- **Blown Fuse**
- **Loss of Voice Prompts**
- **Shutdown in Cold Temperatures**

To see if your unit is affected go to the following website:

http://www.welchallyn.com/support/customer/AED_lookup.jsp

From the EMS News Network

Defibrillators recalled after reported incidents

Welch Allyn is recalling about 14,000 external defibrillators after 39 reported incidents, including two that involved patient deaths.

The recall, announced Tuesday, involves 14,054 AED 10 and MRL JumpStart external defibrillators made between Oct. 3, 2002, and Jan. 25, 2007. The Beaverton, Ore., company says there is a remote chance the devices, available through prescription, may produce low-energy shock, shutdown unexpectedly or be susceptible to electromagnetic noise interference.

The issues might prevent defibrillation of a patient in cardiac arrest and could lead to death, the company said in a statement. The company had received 20 instances of low-energy shock, eight instances of electromagnetic noise interference, and 11 instances of the device unexpectedly shutting down.

To the company's knowledge, the defects of the device did not contribute to the two deaths, said spokesman Jamie Arnold. "Human factors played a role in each incident: damaged device in one and failure to follow directions in the other," he said in an e-mail.

The company said customers should keep AED 10 or MRL JumpStart units in use until they receive replacements because the chance of malfunction is low.

In October 2007, the company announced another recall of 1,794 AED10 automatic external defibrillators. The devices could fail or produce a delay in analyzing a patient's ECG and may not deliver appropriate therapy. This could result in failure to resuscitate the patient. No injuries associated with this product had been reported, but the company had reported 49 failures during internal testing and had received three customer complaints.

For more information, consumers can contact the company at 888-345-5356 or visit http://www.welchallyn.com/AED10Recall.

Any reactions should be reported to the Food and Drug Administration's MedWatch adverse event reporting program at:

http://www.fda.gov/medwatch/report.htm

(http://www.emsnetwork.org/artman2/publish/article_36056.shtml)